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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/632,342

08/01/2003

Jonathan C. Makielski

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06/30/2006

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EXAMINER

PAK, MICHAEL D

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/632,342	MAKIELSKI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michael Pak	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

**DETAILED ACTION**

***Election/Restrictions***

Part I: Types of inventions.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-29, drawn to an isolated and purified polynucleotide, an expression vector, a host cell, a method for producing a polypeptide, classified in Class 435, subclass 69.1.

II. Claims 30-43, drawn to a polypeptide, classified in Class 530, subclass 350.

III. Claim 44, drawn to a purified antibody, classified in Class 435, subclass 387.1.

IV. Claim 45-46, drawn to a method for identifying an agent by sodium channel activity, classified in Class 435, subclass 7.2.

V. Claim 47-48, drawn to a method for identifying an agent by expression of sodium channel mRNA, classified in Class 435, subclass 6.

VI. Claim 48, drawn to a method for determining polypeptide with antibody, , classified in Class 436, subclass 518.

VII. Claim 49, drawn to a method for determining mutation with disease, classified in Class 514, subclass 44.

VIII. Claim 50, drawn to a method for determining risk to Long QT, classified in Class 435, subclass 172.1.

The inventions are distinct, each from the other because of the following reasons.

Art Unit: 1646

The products of any one of the inventions I-III, are distinct each from the other, because they are drawn to products having materially different structures and functions.

Inventions IV-VIII are distinct, each from the other, because they are drawn to processes having materially different process steps, which are practiced for materially different purposes.

The products of inventions I-III, and the process of invention IV-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the alternative inventions I-III can be used in the alternative process of Group IV-VIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classifications and recognized divergent subject matter, and the search required for any one of inventions I-VI is not required for any other invention I-VI, restriction for examination purposes as indicated is proper.

## Part II: Sequences

Furthermore, restriction to one of the following inventions is required under 35 USC 121:

Art Unit: 1646

The inventions as they pertain to one sequence form of the mutant or SEQ ID NO:.

This is a further requirement for restriction into separately patentable groups. Applicant must elect one sequence in order to be fully responsive. Because each receptor requires a unique search of the sequence in the literature databases and undue search burden would be imposed on the examiner if all of the sequences were examined on one patent application.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:30 - 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1646

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michael Pak  
Primary Patent Examiner  
Art Unit 1646  
19 June 2006